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General Law Committee
Opposition to S.B. 121

Senator Maroney, Representative D'Agostino, Senator Witkos and Representative Rutigliano:

As the leading trade association representing manufacturers of medical imaging equipment, radiopharmaceuticals, contrast media, and focused ultrasound therapeutic devices, the Medical Imaging & Technology Alliance (MITA) opposes S.B. 121. MITA urges the Committee **not** to advance this bill given the risks it would create for patient safety, cybersecurity, vulnerability to legal challenge, and significant new and unnecessary costs the bill would create for the State of Conneticut.

Medical device servicing must be safe and effective to protect patient safety

Servicing a medical device is a complex activity that poses a potential range of serious risks to both patients and operators if performed improperly. Uncontrolled distribution and use of proprietary, highly technical service materials by entities that are not required to have appropriate processes and controls in place could lead to improper servicing of a medical device, dramatically increasing risks to patient safety, device performance, and cybersecurity. Safe and effective servicing is not merely a function of acquiring certain documentation or materials—it is the full implementation of and adherence to a set of policies, practices, and procedures that consistently return the device to safe and effective operation.

Medical imaging device servicing requires a high level of technical expertise. This training needs to be regularly updated to reflect knowledge of the latest products, including software and hardware, and a deep understanding of and adherence to current best practices. Operating within a quality management system (QMS) conformant with 21 CFR 820 ensures that devices consistently meet applicable requirements and specifications.

Not only are there potential serious safety concerns with this bill but these concerns would likely increase costs to State medical facilities, in the form of increased litigation stemming from the increased patient safety concerns, increase in medical malpractice insurance, or both. So, in addition to the direct cost to taxpayers in both of these situations, there are also the indirect costs to taxpayers through the likely substantial increases in health insurance and health care programs.

Medical devices are FDA Regulated

Medical device original equipment manufacturers (OEMs) and their authorized service providers are regulated by the United States Food and Drug Administration (FDA) and must adhere to rigorous quality, safety, and regulatory requirements, including 21 CFR 820, when performing maintenance and repair. Independent device service providers are not held to the same rules as OEMs (and their authorized repair providers) when they perform maintenance and repair activities on the same sorts of advanced technology systems. In fact, independent medical device servicing businesses are not currently held accountable for the safety or quality of their work by any authority.

Only OEMs are held by the FDA to high regulatory requirements, including 21 CFR 820, with respect to post-sale servicing of medical imaging equipment. Non-OEM entities are not held to the same quality, safety, and regulatory requirements as are OEMs. Given the ongoing consideration at the federal level, we believe that a patchwork of state laws would directly conflict with the unarguable need for consistency in medical device servicing.

The medical device servicing market is robust and thriving

A recent study estimated that the total number of firms performing medical device servicing in the United States is between 16,520 and 20,830.[1] Furthermore, a separate study estimated that there are 6,500 medical device manufacturers in the U.S.[2] This is clear proof of a thriving marketplace for medical device servicers.

There are a variety of valid business models for medical imaging device servicing. Service models and contractual terms are established at the point of sale, enabling health care facilities to decide what level of servicing they would like to purchase from the manufacturer versus take on themselves or contract out to a third party.

Many OEMs choose to service their own devices. Other medical device companies choose to partner with ISOs to extend their ability to keep their devices operating safely and effectively. Many OEMs establish a contractual relationship to make servicing materials and parts available. Each kind of relationship also differs in its specifics with varying kinds and degrees of support provided under a variety of contractual arrangements.

Given this, purchasers of medical devices and associated servicing activities have a sufficient amount of information to make informed buying decisions.

S.B. 121 would create new and unnecessary cybersecurity risks

Whenever software is installed or adjusted for a medical device, or if software tools are used to access a device for diagnostic and maintenance purposes, the integrity of the software may be compromised. In 2020 alone, 92 individual ransomware attacks occurred that cost an estimated $20 billion, affected over 600 separate clinics, hospitals, and organizations, and jeopardized more than 18 million patient records. Unvalidated software without confirmed authenticity or system integration may present significant potential security vulnerabilities and operational issues. Additionally, expanded and uncontrolled access to medical device operating systems and software applications creates the potential for increased cybersecurity risks, as the opportunity to intentionally or unintentionally introduce security vulnerabilities to the device and to any networks to which the device is connected (e.g. hospital) also expands.

This Legislation Would be Unconstitutional

This bill, if enacted into law, would violate the U.S. Constitution and would be vulnerable to legal challenge. The law would be preempted by federal law, it would be an unconstitutional regulation of interstate commerce, would amount to an unconstitutional taking of property, would unconstitutionally compel speech, and would interfere with existing contracts.

[1] https://www.fda.gov/media/113431/download
[2] https://www.themadeinamericamovement.com/reshoring/u-s-medical-device-industry/

Preemption Under Federal Law

The federal Supremacy Clause—art. VI, cl. 2—gives Congress "the power to preempt state law." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000). Federal law need not expressly displace state law to have preemptive effect. Rather, "state laws are preempted when they conflict with federal law," either because compliance with both federal and state law is "impossibl[e]" or because state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Arizona v. United States*, 567 U.S. 387, 399 (2012). The proposed bill conflicts with, and is therefore preempted by, multiple federal statutory schemes:

1. Patent law. Federal patent statutes embody "a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989). The foundational right granted under federal patent law is the right "to exclude others from making, using, or selling embodiments of their invention." *Biotechnology Indus. Org. v. Dist. of Columbia* ("*BIO*"), 496 F.3d 1362, 1372 (Fed. Cir. 2007).

States' attempts to abrogate or diminish federal patent rights of exclusivity are preempted. In *BIO*, for example, the U.S. Court of Appeals for the Federal Circuit struck down a District of Columbia law restricting prices of patented drugs because it conflicted with, and was therefore preempted by, federal patent law. 496 F.3d at 1374. The court explained that D.C.'s restrictions conflicted with federal patent law because their effect was to "diminish[] the reward to patentees in order to provide greater benefit to District drug consumers." *Id.* The court reasoned that congressional patent policy balanced the competing interests of "reward[ing] innovators with higher profits and … keep[ing] prices reasonable for consumers" by granting innovators a statutory monopoly of limited duration. *Id.* at 1373. The challenged statute purported "to re-balance the statutory framework of rewards and incentives insofar as it relates to inventive new drugs" by restraining prices that D.C. deemed excessive. *Id.* at 1374.

This bill raises similar constitutional concerns. Medical equipment manufacturers—like the pharmaceutical manufacturers at issue in *BIO*—invest enormous sums in research and development, both for their equipment and for the various tools that enable their safe and effective repair.

This bill would also circumvent (and therefore conflict with) federal protections by requiring OEMs to provide "documentation, parts, and tools, inclusive of any updates to information or embedded software." Rather than allowing OEMs to license and distribute their creations to repair providers of their choosing, the bill would compel OEMs to give away their protected property and information, thereby nullifying OEM's statutory rights of exclusivity and financial rewards that promoted their innovation in the first place. That state-law regime undermines the "complex balance of economic forces and regulatory exclusivity designed to encourage and reward the innovation of, research, and development" of new medical technologies and the advanced systems that enable their safe and effective maintenance. *BIO*, 496 F.3d at 1366.

2. Copyright. Similar principles support a preemption argument based on federal copyright law. The copyright statutes reflect Congress's efforts to strike a balance between innovation and public access for creative works by prohibiting the unauthorized use of copyrighted material for a fixed term following the work's publication. *See Eldred v. Ashcroft*, 537 U.S. 186, 212 (2003). Copyright laws have long been held to cover written manuals and other materials reflecting the "original selection or arrangement of facts." *Feist Publications, Inc. v. Rural Tel. Serv. Co.*, 499 U.S. 340, 350 (1991).

Under federal law, OEMs—just like other media creators—have the right to limit the reproduction and access of their copyright-protected repair and training materials, which like their inventions are the product of significant time and investment. By forcing OEMs to provide this

information—even under "fair and reasonable terms"—this bill would upset the federal regime of exclusivity. The bill effectively imposes a state compulsory licensing regime. But when the federal copyright statutes permit such compulsory licensing, they do so expressly. *See* 17 U.S.C. § 155.

Besides erasing OEM's rights of exclusivity, this bill circumvents protective measures manufacturers use to guard their own intellectual property. For that reason, the bill is preempted by the Digital Millennium Copyright Act (DMCA), which Congress enacted to modernize and strengthen copyright protection for digital creations. The DMCA is the exclusive framework governing protective measures against copyright infringement.

3. Trade Secrets. Independently, this bill could require that manufacturers divulge their trade secrets, which conflicts with the federal Defend Trade Secrets Act of 2016 (DTSA). The bill provides: "Nothing in this Act shall be construed to require an original equipment manufacturer to divulge a trade secret to an owner or an independent service provider *except as necessary to provide documentation, parts, and tools on fair and reasonable terms*." This exception swallows the rule. Congress enacted the DTSA to "improv[e] trade secret protection" and thereby to "incentivize future innovation while protecting and encouraging the creation of American jobs." S. Rep. No. 114-220, at 3. To further those goals, DTSA prohibits the misappropriation of trade secrets, imposes criminal penalties for violations, and provides the holders of trade secrets with a range of remedies to prevent misappropriation, including private suits for injunctions. *See* 18 U.S.C. § 1836(b)(3). State laws compelling the unauthorized disclosure of trade secrets undercut the protective purpose of the DTSA, and thus raise preemption questions. This bill strips protection from OEM's repair-related information, much of which is proprietary and sensitive and therefore falls within the definition of a trade secret under state and federal law.

Regulation of Interstate Commerce

The Commerce Clause gives Congress the power "[t]o regulate Commerce with foreign Nations, and among the several States." U.S. Const., Art. I, § 8, cl. 3. The Supreme Court has "long interpreted the Commerce Clause as an implicit restraint on state authority, even in the absence of a conflicting federal statute." *United Haulers Ass'n, Inc. v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 550 U.S. 330, 338 (2007). This "further, negative command" is "known as the dormant Commerce Clause." *Comptroller of the Treasury v. Wynne*, 135 S. Ct. 1787, 1794 (2015). As relevant here, a state law can violate the dormant Commerce Clause either by directly regulating out-of-state conduct or by imposing excessive burdens on interstate commerce. This bill would do both.

This bill would *directly* regulate commerce outside the state. A state law applies "extraterritorially" if it either expressly applies to out-of-state commerce or has that "practical effect." *Assoc. for Accessible Med. v. Frosh (AAM)*, 887 F.3d 664, 668 (4th Cir. 2018). Courts generally invalidate such laws "without further inquiry." *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 579 (1986). In *AAM*, for example, the U.S. Court of Appeals for the Fourth Circuit struck down a Maryland law that banned "price gouging" because although the statute by its terms applied only to pharmaceuticals "made available for sale" in Maryland, it had the "practical effect" of regulating prices in "upstream" transactions occurring "almost exclusively" outside of the state. 887 F.3d at 672-73 (citing *Brown-Forman*, 476 U.S. at 580). Although price controls like those struck down in *AAM* quintessentially violate the extraterritoriality rule, the rule also forbids non-price regulations that affect commerce nationwide. *See, e.g.*, *Sam Francis Found. v. Christies, Inc.*, 784 F.3d 1320, 1323-25 (9th Cir. 2015) (en banc).

Under these principles, this bill would have an unlawful extraterritorial effect. In effect, the State is commanding out-of-state businesses to provide a host of materials and services to in-state businesses, simply because the out-of-state business's products have wound up in the state. In addition, the bill would compel manufacturers to disclose sensitive and proprietary information. Once unauthorized third parties

gain access to that information, its value, which inheres in its secrecy, is lost forever—not just within the state but *nationwide*. Under the Commerce Clause, the state lacks any "valid … authority" to "project[] its legislation into other states." *Brown-Forman,* 476 U.S. at 583-84.

Setting extraterritoriality aside, the bill raises concerns under the so-called "*Pike* balancing test" because it would impose burdens on interstate commerce that are "clearly excessive in relation to the putative local benefits." *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970). Medical device manufacturers sell their lifesaving devices to medical providers across the nation. Once patented tools and technologies are made available in the marketplace and copyrighted materials are freely accessible, that material loses protection everywhere.

Taking of Property

Under the Fifth Amendment, "private property [shall not] be taken for public use, without just compensation." That prohibition prevents public officials from taking or destroying the value of private property without providing adequate compensation. The Supreme Court has long held that the Takings Clause protects intellectual property, including trade secrets, just as it does physical property. *See Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1002-04 (1984). Courts apply two modes of analysis in reviewing takings challenges, depending on whether the challenged taking is "categorical" or "regulatory." This bill triggers both modes of analysis.

The bill constitutes an unlawful regulatory taking under the analysis set out in *Penn Central Transportation Co. v. City of New York*, 438 U.S. 104 (1978). *Penn Central* describes three factors relevant to an analysis of a regulatory taking: (1) the economic impact of the regulation on the claimant, (2) the extent to which the regulation interfered with the claimant's investment-backed expectations, and (3) the character of the government action. *Id.* at 124. Applying these factors, the bill is unconstitutional. OEMs invest enormous sums in the development of their products and in the tools and material necessary for safe and effective repair. They do so with expectations about their ability to exclude, through contracts and under federal patent and copyright laws, access by unauthorized and unqualified individuals. The economic impact of stripping away OEM's rights of exclusivity will be immediate and significant.

Compelled Speech

The bill also compels OEMs to disclose a broad array of materials, including written documentation and service access methods, to independent service repair providers who have no commercial relationship with the OEM. In doing so, the bill violates the First Amendment's guarantee of the freedom of speech. The First Amendment has long been held to "prohibit[] the government from telling people what they must say." *Rumsfeld v. Forum for Acad. & Inst. Rights, Inc.*, 547 U.S. 47, 61 (2006).

The bill violates that principle by compelling OEMs to divulge commercially sensitive information about their products. Because the bill targets a discrete set of actors (medical equipment manufacturers) and compels the disclosure of a specific type of content (that which the State deems necessary for repairing medical equipment), the bill is a "speaker-based" and "content-based" mandate, meaning that a reviewing court should apply heightened scrutiny. *See Sorrell v. IMS Health Inc.*, 564 U.S. 552, 573 (2011); *Reed v. Town of Gilbert*, 135 S. Ct. 2218, 2226 (2015). Under heightened scrutiny, such laws "are presumptively unconstitutional." *Reed*, 135 S. Ct. at 163.

Requiring OEMs to turn over all manner of repair-related information, parts, and tools—even at a "fair and reasonable" price—is not "narrowly tailored" to serve a sufficiently "compelling" government interest. *Id.* at 171. To be sure, the State would also likely assert that the law is justified by public-health concerns stemming from alleged delays in repairing equipment or higher prices for repairs. But while

public-health concerns *can* be "compelling," the government must point to a specific problem that justifies "differentiation" between medical equipment manufacturers and other entities that support public-health infrastructure. *Id.* Moreover, the State may need to define its interest with greater specificity in order to assess whether the treatment fits the State's need. Even if the bill furthered a substantial state interest, the bill is not narrowly tailored because it unnecessarily threatens the permanent destruction of OEM's valuable intellectual property. There are also alternative ways that the State could further its interests.

The State could respond that the bill either (1) does not regulate speech at all and instead requires the provision of products and services that manufacturers already offer, or alternatively (2) regulates "commercial speech" and is therefore subject to lesser scrutiny under *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557 (1980). Neither argument would have merit. First, the bill does not simply require manufacturers to perform services, but rather requires them to disseminate information and materials about the use of their products. These forms of information are expressive (as suggested by their copyright protection) and thus there is a strong argument that compelling the disclosure of this information is compelling *speech*: "The law here, like the Vermont law in *Sorrell*, 'does not simply have an effect on speech, but is directed at certain content and is aimed at particular speakers.'" *APAC*, 140 S. Ct. at 2347 (quoting *Sorrell*, 564 U.S. at 567). Second, the notion that the bill compels only "commercial speech" has lost significant force following the Supreme Court's recent decision in *APAC*. There, the plurality opinion applied strict scrutiny rather than *Central Hudson* in holding that Congress could not constitutionally exempt government-debt collectors from its ban on robocalls. 140 S. Ct. at 2347. Regardless, laws subject to *Central Hudson* must still be "narrowly tailored to serve a significant governmental interest," *id.* at 2356 (Sotomayor, J., concurring), and for the reasons explained above, there are credible arguments that the bill would fail that test, as well.

Interference with Contracts

Finally, the bill implicates the federal Contracts Clause, which provides that "[n]o State shall … pass any … Law impairing the Obligation of Contracts…." Art. I, § 10, cl. 1. A state law violates the Contracts Clause when it (1) operates "as a substantial impairment of a contractual relationship," and (2) is not "an appropriate and reasonable way to advance a significant and legitimate public purpose." *Sveen v. Melin*, 138 S. Ct. 1815, 1822 (2018). Existing contracts between manufacturers and medical service providers establish clear permissions and restrictions on the use of the equipment and related documents and materials. This exclusivity is a substantial component of the parties' bargain.

The express purpose and inevitable effect of the bill is to fundamentally alter those terms by abolishing the right to restrict third parties from accessing manufacturers' technology. In other words, a state law requiring protected information to be divulged to third parties substantially reduces the value of these existing negotiated contracts and thus inherently "impair[s]" them. And just as the bill is not narrowly tailored to any compelling government interest in the First Amendment context, and interferes with investment-backed expectations in the takings context, the bill arguably is not an appropriate and reasonable way to advance a significant and legitimate public purpose.

Conclusion

Our position is that all entities engaged in servicing medical devices should be held to consistent quality, safety, and regulatory requirements and that the intellectual property rights of medical device innovators must be protected. If enacted, this legislation would create new and unnecessary risks to patient safety, devastate the IP rights of medical device innovators, and lead to costly and protracted implementation, enforcement, and litigation risk for the State of Conneticut, encumbering the State's budget. For these reasons, we urge the Committee to not advance this bill.

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If you have any questions, please contact Laura Srebnik, Manager, Government Relations at lsrebnik@medicalimaging.org or 703- 841-3247.

Sincerely,

Medical Imaging & Technology Alliance

MITA is the collective voice of manufacturers of medical imaging equipment, radiopharmaceuticals, contrast media, and focused ultrasound therapeutic devices. It represents companies whose sales comprise more than 90 percent of the global market for medical imaging innovations. These products include: magnetic resonance imaging (MRI), medical X-Ray equipment, computed tomography (CT) scanners, ultrasound, nuclear imaging, radiopharmaceuticals, and imaging information systems. MITA Member company technologies are an important part of our nation's healthcare infrastructure and are essential for the screening, diagnosis, staging, managing and effectively treating patients with cancer, heart disease, neurological degeneration, and numerous other medical conditions.